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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

01-SWR-WL-39/7

April 20, 2001

John R. Hanson
Co-Owner
Club Fitness
1508 Macon Drive, Building C
Little Rock, AR 72211

Dear Mr. Hanson:

The inspection of your tanning facility, Club Fitness located at 1508 Macon Drive, Building C, Little Rock, AR 72211 on February 5, 2001, by Investigator Scotty Hargrave revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). The investigator documented significant items of noncompliance with the Federal Performance Standard for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations, Part 1040.20 (21 CFR 1040.20) in conjunction with tanning beds in operation at your facility. The inspection indicated noncompliances for the tanning beds manufactured by Sun Industries.

The inspection revealed that the tanning beds located at your facility were misbranded within the meaning of Section 502(f) of the Act as a result of actions taken by your firm. The tanning beds do not provide the users with means to manually terminate radiation emission as necessary for the protection of users against potentially harmful exposure to ultraviolet radiation [21 CFR 1040.20(c)(3)]. The tanning beds were not labeled with a danger statement or exposure schedule as required by 21 CFR 1040.20(d). In addition, there was no documentation of lamp compatibility available for the lamps installed in the tanning beds to provide adequate protection of users against potentially harmful exposure to ultraviolet radiation [21 CFR 1040.20(e)(1)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies regarding sunlamp products at your firm. It is your responsibility to ensure that electronic sunlamp products are maintained so that they continue to comply with the provisions of the Act. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

You should notify this office in writing within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Deborah M. McGee, Radiation Specialist, U.S. Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982, telephone (214) 655-8100, ext. 138.

Sincerely,

Gary L. Pierce
Regional Food and Drug Director
Southwest Region